



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Certificate of Analysis Finished Product			
Title	:		
Product Name	OMEECAN Injection	A.R. No.	ARN/FP/26/032
Generic Name	Omeprazole for Injection 40mg	Sampled qty.	45 Vials
Batch No.	ARN2630A	Sampled by	Rakesh
Batch Size	1,00,000 Vials	Sampled on	06/07/2026
Mfg. Date	06/2026	Date of Testing	07/07/2026
Exp. Date	05/2028	Date of Release	24/07/2026

S. No.	Tests	Specifications	Observations		
1.	Description	A white dry powder filled in amber glass vial.	A white dry powder filled in amber glass vial.		
2.	Identification (By HPLC)	In the Assay, the principal peaks in the chromatogram obtained with the test solution correspond to the peak in the Chromatogram obtained with the working standard solution.	Complies		
3.	Uniformity of weight	Average weight $\pm 10\%$	-4.48% & +4.51%		
4.	Average weight	Informative $\pm 2\%$.	121.2 mg		
5.	pH	10.30 to 11.30	10.61		
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/vial NMT 600/vial Constitute the injection as directed on the label; The solution is essentially free from particles of foreign matter that can be seen on visual inspection.	1,394/vial 2/vial Complies		
7.	Water (By KF)	NMT 3.0%w/w	0.93%w/w		
8.	Sterility	Dry Injection should comply the test for sterility.	Complies		
9.	Bacterial Endotoxins	NMT 5.0 EU/mg of Omeprazole Sodium.	Less than 5.0 EU/ mg of Omeprazole Sodium.		
10.	Assay: (By HPLC) Each glass vial contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Omeprazole Sodium (Sterile) IP (Lyophilized) Equivalent to Omeprazole		40 mg	40.7451mg	101.86%	90.0 to 110.0%

Remarks: In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/IHS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SURJEET KAUR	Approved by NAME: MRS. SWATI DHAWAN
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